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SIPDIS

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SUBJECT: PHARMACEUTICAL INTELLECTUAL PROPERTY RIGHTS (ZAMBIA)

REF: LUSAKA 211

11. (SBU) Summary. Although counterfeit medicines are prevalent on the local market, the GRZ has not determined the extent of the problem and its implications on the economy and public health. Zambian regulatory institutions lack resources to carry out their mandate, and this shortcoming might contribute to some corrupt activities in GRZ drug procurement. The counterfeit medicines pose health risks to consumers and have resulted in numerous alleged deaths. This cable also outlines other problems in the general enforcement of intellectual property rights in Zambia. End Summary.

Scale of the problem unclear

12. (SBU) A Pharmaceutical Society of Zambia official advised Embassy Commercial Assistant that there is an influx of counterfeit pharmaceutical products in Zambia, but that the scale of the problem is not clear. This was corroborated by Pharmaceutical Regulatory Authority (PRA) Director General, Esnat Mwape, who explained that the PRA has confiscated counterfeit medicines and issued public warnings. Embassy contacts opine that the most prevalent counterfeit pharmaceutical products are over the counter painkillers, such as Panadol (a registered brand that contains paracetamol), and prescription antibiotics, such as ampicillin and tetracycline.

13. (SBU) The GRZ established the Pharmaceutical Regulatory Authority in 2006 to oversee public and private health care providers as well as pharmaceutical suppliers. The PRA is responsible for registering pharmaceutical dealers, inspecting medical facilities, and providing pharmaceutical testing services. The PRA has procured two minilab test kits, to perform basic tests on imported pharmaceuticals, and has installed one at the National Institute for Scientific and Industrial Research to support inspections at Lusaka International Airport. It intends to install the other at the high-volume Chirundu land border with Zimbabwe. The minilab kits require significant support from the National Drug Quality Control Laboratory to process and analyze specimens and generally are unable to identify counterfeit medicines. The PRA lacks financial, technical, and human resources to enforce its mandate. According to embassy information, the PRA currently employs four inspectors.

14. (U) To date, the PRA inspectors have directed their attention to reputable pharmacies in more affluent commercial districts. They have neglected the lesser known, yet perhaps more popular, pharmaceutical outlets in the bustling shopping areas frequented by low-income consumers. These outlets, which stock their shelves with the cheapest available products, are perhaps the most likely

distribution points for counterfeit medicines. A December 4, 2007, article in a state-owned daily newspaper, the Times of Zambia, appealed to the PRA to conduct regular unannounced inspections of these outlets, adding that "it is a common sight nowadays to see drugs, especially antibiotics, displayed next to soaps, lotions, batteries, and confectionaries in dust strewn, sun streaked shops in the market or [at] bus stations."

15. (SBU) In a previous meeting with the Ambassador and Embassy HIV/AIDS relief program administrators, Health Minister Brian Chituwo acknowledged the problem of counterfeit medicines and the lack of GRZ resources. Chituwo requested USG support to establish a pharmaceutical quality laboratory to ensure drug safety and efficacy. Embassy representatives responded that the AIDS relief program funding could only be applied to HIV/AIDS projects, but communicated the request to Embassy PolEcon section.

Problem may point to corruption

16. (SBU) There are no reports of intellectual property violations concerning medicines procured through the World Health Organization or donor funded programs such as the President's Emergency Plan for AIDS Relief (PEPFAR). A manager of a USAID project in Zambia told Embassy Commercial Assistant that counterfeit antiretroviral drugs (ARVs) have not been a problem in Zambia in recent years. One embassy contact suggested that the availability of free ARVs through PEPFAR has dramatically diminished the market for fake products.

17. (SBU) Conversely, in numerous instances medicines procured through GRZ resources or directly by individuals/retailers have been found to be counterfeit. For example, an anti-malaria treatment drug, Fansidar, that the Ministry of Health supplied to Zambia's

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third largest hospital, Kitwe General Hospital, was found to contain chalk. In response, the hospital stopped using the product, but did not investigate the matter further. Caroline Yeta, PRA Director of Inspections, confirmed other cases of counterfeit over the counter anti-malaria medicines, such as fake Co-Arinate, which she said originates in China.

18. (SBU) Medical Stores Limited (MSL), a relatively well-managed government warehouse/distributor located in Lusaka, is responsible for supplying medical products to public hospitals and health centers on behalf of the Ministry of Health. MSL undertakes random (spot-check) qualitative tests on some of its medicines at its warehouse before distributing the products. Many districts and hospitals do their own procurement, however, and the products are purchased and delivered without MSL oversight. One mission development officer speculated that it is at this point that counterfeit medicines most likely sneak into the GRZ system.

19. (SBU) The lack of GRZ resources to regulate the pharmaceutical industry creates opportunities for corrupt activities in GRZ drug procurement. In February 2007, a Lusaka Magistrate found a former Ministry of Health Permanent Secretary, Kashiwa Bulaya, guilty of corruption in a case involving a government contract to purchase HIV/AIDS medication (Ref A). The prosecution revealed that Bulaya was not concerned about the efficacy of the product (an untested natural herb remedy) and had awarded a contract for personal gain. In its draft national anti-corruption strategy, the GRZ is proposing a new Procurement Act, which has the potential of reducing the incidences of counterfeit medicines in GRZ facilities.

Markets exporting counterfeit medicines

110. (SBU) According to a local expert, most counterfeit medicines in Zambia originate in India and China. He speculated that legitimate Zambian pharmaceutical companies manufacture a relatively small amount of the counterfeit non-prescription products. Although it would be relatively easy to trace these medicines from the retailer to the manufacturer, inspectors have not yet done so. Because of

their size and reputation, these companies are seldom inspected by the PRA.

¶11. (SBU) The expert opined that the imported products enter Zambia through the Mwami land border post with Malawi because of its lax customs enforcement. Importers and vendors are primarily Indians who own shops on both sides of the border. He expressed his view that organized crime syndicates bring in counterfeit goods, including some pharmaceutical products, through Lusaka International Airport with the collusion of airport employees, customs officers, and senior GRZ officials.

Health dangers of counterfeit medicines

¶12. (U) Chipupu Kandeke of the Church Health Association of Zambia (CHAZ) warned that some counterfeit medicines have dangerous ingredients, which could be fatal if consumed in large quantities. He also noted that pharmaceutical products with low active ingredient content, such as ampicillin and tetracycline, can cause resistant strains to emerge.

¶13. (U) In mid-2007, a private television station reported that twelve girls in Petauke District, Eastern Province, died after taking anti-malaria tablets at a public health center. Subsequent laboratory tests, according to the same report, revealed that the anti-malaria tablets were counterfeit. To Post's knowledge, the GRZ has not issued a statement on the deaths, or explained the presence of the allegedly counterfeit pharmaceuticals at the public health center. GRZ authorities also have not made any public announcements about planned preventative measures that they will implement to avoid future incidences.

Broader IPR Challenges

¶14. (U) A number of factors impede the general enforcement of intellectual property right in Zambia, including:

--slow litigation (IPR cases are adjudicated by High Courts, which meet less frequently than subordinate courts and are overburdened with cases);

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--law enforcement regulations that prohibit police officers below the rank of Inspector from conducting searches, making arrests, and confiscating pirated material;

--lack of coordination of national policy and regulations (currently, the Ministry of Information is responsible for piracy and copyright issues, the Ministry of Commerce, Trade, and Industry is responsible for patents and standards, and the Ministry of Health is responsible for pharmaceutical registration); and

--inadequate, non-TRIPS-compliant legislation (as a member of the Least Developed Countries, Zambia is not required to have TRIPS-compliant patent legislation in place until 2016).

Comment

¶15. (SBU) The continued presence of counterfeit medicines suggests that the situation has not improved in recent years, despite the creation of the PRA. In its 2008 Activity Plan, the PRA included counterfeit medicine detection training for its staff, which will also consist of guidance for carrying out "door-to-door" inspections of retail outlets. Although this should enhance its ability to combat IPR violations and/or counterfeit products, the PRA will still be in dire need of additional resources. To date, the PRA has hired only four inspectors and has yet to recruit laboratory personnel.

¶16. (U) The media also has a role to play in sensitizing the public to the dangers of counterfeit products. Even with ample media coverage, however, it will continue to be difficult for consumers to distinguish between genuine and counterfeit medicines. Regrettably, the Zambian public--particularly the majority who live below the poverty line--will continue to be drawn to the cheapest products available and to less-reputable retail outlets, despite the prevalence of counterfeit medicines at these locales, because of a perceived lack of affordable alternatives.

KOPLOVSKY